Our Ref. No.: 003764.P002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
Pinaki Ray	Examiner: **Williams, Catherine Serke**
Application No.: **09/475,768**	Art Unit: **3763**
Filed: **December 30, 1999**	Confirmation No.: **6849**
For: **CONDUIT SYSTEM FOR ISOLATION OF FLUIDS IN BIOLOGICAL TISSUES**	

REPLY BRIEF

Mail Stop Appeal Brief - Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's Answer mailed November 25, 2005, Applicant submits the following Reply Brief.

A. Rejection of Claims 1-9, 12-13 & 48-60 as Obvious Over Boddie in view of Aigner

The Patent Office rejects claims 1-9, 12-13 and 48-60 under 35 U.S.C. §103 as obvious over Boddie over Aigner. The Patent Office relies on this combination to reject the noted claims by arguing among other things that a description of the external accessibility of channels of a patient in the claims is readable on an open chest cavity procedure; and there is a motivation to combine Aigner with Boddie, because Boddie notes that in certain instances, ligatures around a point of a splint catheter are difficult and a balloon prevents undue organ damage. Applicant offers the following analysis of each of these points.

1. Externally Accessible

The Patent Office admits in its Examiner's Answer that Boddie and Aigner each teach open chest cavity procedures. The Patent Office argues that Boddie teaches external accessibility of a channel despite its teaching of an open chest cavity procedure. The Patent Office cites *The American Heritage® Dictionary of the English Language, Fourth Edition* for a definition of "externally" and "accessible." According to the definition of externally, the definition includes:

1. Relating to, existing on, or connected with the outside or an outer part; exterior.

Femoral arteries, radial arteries and jugular arteries all meet this definition in that they relate to or exist on an outside part of the human body. Albeit, each artery is beneath the skin, the artery still relates to the external portion of a patient's body. Quite the contrary, a hepatic artery, a hepatic vein, a portal vein, the inferior vena cava, etc. as described in Boddie are not external in terms of the definition provided by the Patent Office. Only by opening the chest cavity does Boddie teach accessing these vessels.

With respect to the definition of "accessible," *The American Heritage® Dictionary of the English Language, Fourth Edition* includes:

1. Easily approached or entered.

Relatively speaking, a percutaneous access via a radial artery, a femoral artery, or a jugular vein is easily approached or entered relative to, for example, an open chest cavity procedure. Only by ignoring the arduous task of opening the chest cavity may a hepatic artery or vein, or a portal vein be considered easily approached or entered according to Boddie and Aigner. It is a strain on the definition and the claim language to ignore the opening of a chest cavity in the context of determining whether a delivery conduit or a collection conduit has a length measured from an externally accessible channel of a patient.

2. No Motivation to Combine the Teachings of Aigner with Boddie

The Patent Office argues that Aigner provides motivation to modify the ligatures of Boddie within an occlusion balloon because positioning ligatures around vessels can present a problem by potentially damaging surrounding organs and an occlusive balloon solve this problem.

In the Appeal Brief, Applicant argued that, upon its understanding Boddie, Boddie utilizes several ligatures primarily to conformably engage and releasably hold catheters to arteries or veins, not to block them. Accordingly, substituting a balloon for any of these ligatures would not be suitable. Applicant also pointed out that Boddie does teach one ligature used to occlude the hepatic artery to prevent blood flow into the liver. See col. 3, lines 40-42. This ligature is associated with a delivery conduit as identified by the Patent Office, not a collection conduit. Applicant pointed out that, in its understanding of Boddie, to substitute a balloon for the ligature preferred by Boddie, one presumably would have to branch first branch catheter 35 in a direction downstream (towards the liver) and a position upstream. This separate branching of first branch catheter 35 is not taught by Boddie. Nevertheless, one must read into Boddie presumably that the upstream-directed branch would contain the balloon catheter portion. These presumptions are not taught anywhere in Boddie or Aigner. Applicant also noted that even if a balloon catheter was utilized as Applicant (not Boddie or Aigner) has described, a ligature would still likely be necessary to stop blood flow while the branch device is placed. In such case, a ligature would be necessary. Therefore, there is no reason for a balloon and there is no benefit for utilizing a balloon since a ligature is still necessary. In other words, a balloon and a ligature does not necessarily prevent the potential problem noted by the Patent Office by the use of ligatures around a vessel, since the ligature would arguably still be necessary.

The Patent Office equates catheter 41 of Boddie as a collection conduit. According to Applicant's understanding of Boddie, however, catheter 41 does not collect a fluid but instead routes blood flowing from the hepatic artery to the heart. At best, tube 61 might qualify as a collection conduit. "[I]f one follows the route of the blood flow that is designated by single-headed arrows in FIG. 3 (i.e., the blood that is flowing in the general circulatory system), and compares it with the route of the blood flow that is designated by double-headed arrows in

FIG. 3 (i.e., the blood flow that is limited to and from the cancer-involved liver by the use of my invention), then one can readily see how my invention structurally and successfully accomplishes the function of selectively isolating the liver's blood circulation from the blood circulation of the rest of the body. . . ." Col. 3, lines 53-55. According to this description, Figure 3 shows first catheter 41 routing blood from the hepatic artery to the heart. Tube 61 extends through catheter 41 and presumably into the hepatic vein to collect fluid (blood) from the liver. Tube 61 is not engaged or releasably held to a blood vessel by a ligature. Instead, tube 61 is positioned through catheter 41 and presumably engaged or releasably held by catheter 41, not a ligature. Boddie solves the alleged motivation of minimizing damage surrounding organs by routing tube 61 through another catheter. Thus, a need for a ligature or a balloon is avoided. In other words, there would be no motivation to associate a balloon with tube 61 particularly where Boddie describes routing tube 61 through catheter 41.

For the above stated reasons, claim 1 is not obvious over the cited references. Claims 2-9 and 12-13 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 2-9 are not obvious over the cited references.

Independent claim 48 describes a delivery conduit and a collection conduit comprising a collection seal for occluding fluid flow by the collection seal. Each of the delivery conduit and the collection conduit has a length dimension suitable to be positioned by a percutaneous transluminal route from an externally accessible channel of a patient.

Claim 48 is not obvious over the cited references for the reasons noted above with respect to claim 1. Namely, neither Boddie nor Aigner describe a length dimension of a delivery conduit and a collection conduit suitable to be positioned by percutaneous transluminal routes from externally accessible channels. Further, as noted above with respect to claim 1, there is no motivation to combine Boddie and Aigner, because Boddie does not need a ligature or balloon on tube 61, the conduit identified as a collection conduit in the reference made by the Patent Office or to be used as an occlusion device, it does not appear practical or even feasible to occlude a hepatic artery.

Claims 49-60 depend from claim 48 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 48, claims 49-60 are not obvious over the cited references.

Applicant respectfully requests the Patent Office withdraw the rejection to claims 1-9, 12-13 and 48-60 under 35 U.S.C. §103(a).

B. Rejection of Claims 10-11 as Obvious Over Boddie

Claims 10-11 are rejected as obvious over Boddie in view of Aigner. The Patent Office believes the claims recite functional aspects. Applicant respectfully disagree. By specifying a biological mass as a human heart (claim 10), a length dimension of a delivery conduit and a collection conduit are further specified. This is not a functional aspect but contributes to a structural interpretation of structural elements of claim 1.

Similarly, claim 11 provides a structural limitation to the delivery conduit by giving it a size (e.g., an exterior diameter).

The combination of Boddie and Aigner do not teach the limitations of either claim 10 or claim 11. Applicant respectfully requests the Patent Office withdraw the rejection to claims 10-11 under 35 U.S.C. §103(a).

C. Rejection of Claims 61-64 as Obvious Over Boddie in view of Aigner and Obvious over Sterman

Claims 61-64 describe the first and second externally accessible channels for independent claim 1 and independent claim 48. As noted above, externally accessible channels such as a femoral artery, a radial artery and a jugular vein are not described by either Boddie or Aigner which relate to open chest cavity procedures as admitted by the Patent Office. Claims 61-64 thus add structural aspects to the system in that they further define the length dimension of a delivery conduit and/or a collection conduit.

For the above-stated reason and the reasons stated with respect to independent claims 1 and 48, Applicant respectfully requests that that Patent Office withdraw the rejection to claims 61-64 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN, LLP

Dated: 1/24/06

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CERTIFICATE OF MAILING

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Nedy Calderon 1/24/06

Nedy Calderon Date

AF/ZPW

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application No.	09/475,768
Filing Date	December 30, 1999
First Named Inventor	Pinaki Ray
Art Unit	3763
Examiner Name	Williams, Catherine Serke
Total Number of Pages in This Submission	9
Attorney Docket Number	3764P002

ENCLOSURES *(check all that apply)*

- [X] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Response
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
  - [ ] PTO/SB/08
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Basic Filing Fee
  - [ ] Declaration/POA
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s)
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [X] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) *(please identify below):*

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	William Thomas Babbitt, Reg. No. 39,591 BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP
Signature	William T Babbitt
Date	January 24, 2006

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Typed or printed name	**Nedy Calderon**		
Signature	Nedy Calderon	Date	**January 24, 2006**

Based on PTO/SB/21 (09-04) as modified by Blakely, Sokoloff, Taylor & Zafman (wlr) 11/30/2005.
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FEE TRANSMITTAL for FY 2005

Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27.

TOTAL AMOUNT OF PAYMENT ($) 0.00

Complete if Known	
Application Number	09/475,768
Filing Date	December 30, 1999
First Named Inventor	Pinaki Ray
Examiner Name	Williams, Catherine Serke
Art Unit	3763
Attorney Docket No.	3764P002

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☒ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 02-2666 Deposit Account Name: Blakely, Sokoloff, Taylor & Zafman LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below
☐ Charge fee(s) indicated below, except for the filing fee
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☒ Credit any overpayments

FEE CALCULATION

1. EXTRA CLAIM FEES

			Extra Claims		Fee from below		Fee Paid
Total Claims	30	- 47** =	0	x	50.00	=	$0.00
Independent Claims	2	- 4** =	0	x	200.00	=	$0.00
Multiple Dependent						=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	50	2202	25	Claims in excess of 20
1201	200	2201	100	Independent claims in excess of 3
1203	360	2203	180	Multiple Dependent claim, if not paid
1204	790	2204	395	**Reissue independent claims over original patent
1205	300	2205	150	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (1) ($) 0.00

***or number previously paid, if greater, For Reissues, see below*

2. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
2053	130	2053	130	Non-English specification	
1251	120	2251	60	Extension for reply within first month	
1252	450	2252	225	Extension for reply within second month	
1253	1,020	2253	510	Extension for reply within third month	
1254	1,590	2254	795	Extension for reply within fourth month	
1255	2,160	2255	1,080	Extension for reply within fifth month	
1401	500	2401	250	Notice of Appeal	
1402	500	2402	250	Filing a brief in support of an appeal	
1403	1,000	2403	500	Request for oral hearing	
1451		2451		Petition to institute a public use proceeding	
1460	130	2460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
1809	790	1809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	

Other fee (specify) _____

SUBTOTAL (2) ($)

SUBMITTED BY

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